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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,961	07/05/2003	Christian E. Schafmeister	214001-01024-1-1	9015

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EXAMINER

DESAI, RITA J

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/613,961	<b>Applicant(s)</b> SCHAFMEISTER, CHRISTIAN E.	
	<b>Examiner</b> Rita J. Desai	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 13-294 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/08/03</u> . | 6) <input type="checkbox"/> Other: ____  |

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicants have elected group I of the restriction without traverse.

Claims 1-12 are pending.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites first amine protecting group, second amine protecting group, functional group and strongly activated ester. All these terms are overly broad and hence not clear which group the applicant actually means it to be.

Applicant can overcome this by inserting the specific groups.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites R5 is N3 or NR2Y. It is not clear if applicants mean the N to be tertiary or do the 3 links include the pyrrolidine ring.

Clarification is needed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The formula I indicates R5 to be N3 or NR2Y which would indicate that the N has 4 groups attached to it making it tertiary. The specifications and the figures which have the diagrams do not indicate it to be such. They all indicate that the N has a total of 3 groups linked to it.

Correction/Clarification is required.

***Claim Rejections - 35 USC § 102***

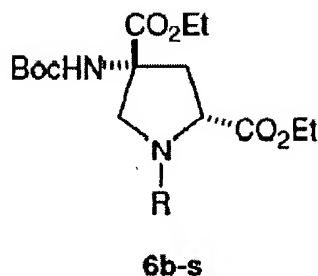
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by

Synthesis and metabotropic glutamate receptor antagonist activity of N1-substituted analogs of 2R,4R-4-aminopyrrolidine-2,4-dicarboxylic acid  
Valli, Matthew J.; Schoepp, Darryle D.; Wright, Rebecca A.; Johnson, Bryan G.; Kingston, Ann E.; Tomlinson, Rosemarie; Monn, James A.

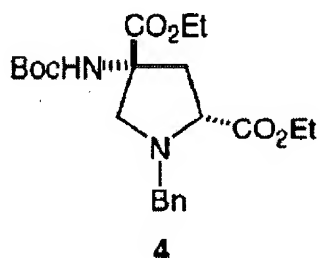
1998

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The reference discloses compound of the formula

and



These read on the applicants compounds if the NR<sub>2</sub>Y is Meant to be NRY and , wherein Y and X are protecting groups.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

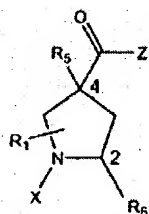
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claim 1-12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Valli M et al 1998.

Synthesis and metabotropic glutamate receptor antagonist activity of N1-substituted analogs of 2R,4R-4-aminopyrrolidine-2,4-dicarboxylic acid  
Valli, Matthew J.; Schoepp, Darryle D.; Wright, Rebecca A.; Johnson, Bryan G.; Kingston, Ann E.; Tomlinson, Rosemarie; Monn, James A.

Applicants compounds are drawn to compounds of the formula



(I)

5

where:

X represents a first amine protecting group;

Y represents a second amine protecting group;

Z represents a weak leaving group;

10 R<sub>1</sub> represents an H, or a functional group, and can be attached to the molecule at positions 2, 3 or 5;

R<sub>2</sub> represents an H or a functional group;R<sub>3</sub> represents N<sub>3</sub> or NR<sub>2</sub>Y;R<sub>6</sub> represents a carboxylic acid or a strongly activated ester; and

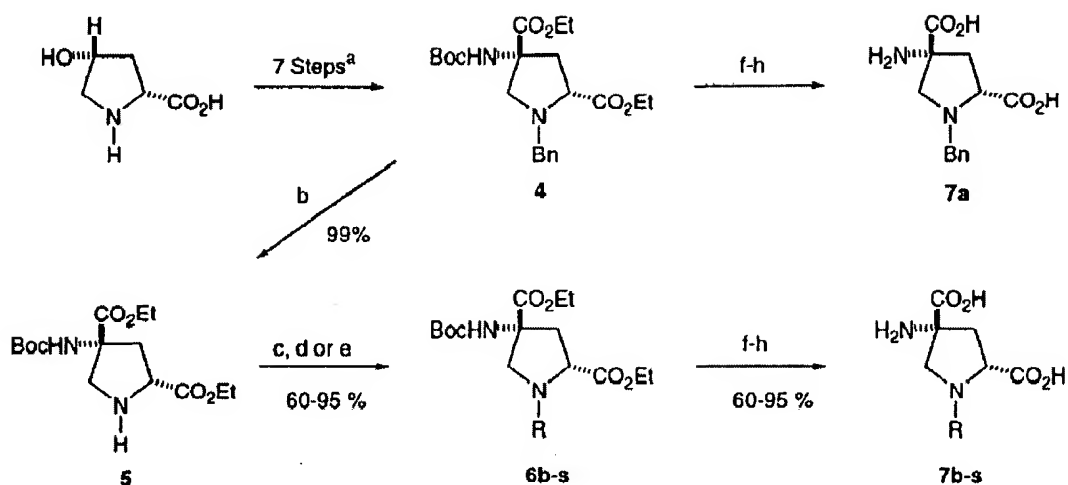
5 the stereochemical configuration at positions 2 and 4 and of the carbon bearing R<sub>1</sub>

(if R<sub>1</sub> is not H) can be any one of (S,S,S), (S,S,R), (S,R,S), (S,R,R), (R,S,S),

Determination of the scope and content of the prior art (MPEP §2141.01)

The reference teaches the following compounds, see below;

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Compound 6 or 7

R

- a benzyl
- b methyl
- c ethyl
- d 2-chlorobenzyl
- e 3-chlorobenzyl
- f 4-chlorobenzyl
- g 3,4-dichlorobenzyl
- h 2,6-dichlorobenzyl
- i 2,4-dichlorobenzyl

Compound 6 or 7

R

- j diphenylmethyl
- k 2,2-diphenylethyl
- l 3,3-diphenylpropyl
- m 1-naphthylmethyl
- n 2-naphthylmethyl
- o 2-phenylbenzyl
- p 4-phenylbenzyl
- q cyclohexylmethyl
- r 2-phenylethyl

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The various N protecting groups are but they are not the specific ones as given in 6-8.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

There are several N-protecting groups known and since the function is the same one of skill in the art would find it obvious to use any of the groups.

### Conclusion

Claims 1-12 are not found to be allowable.

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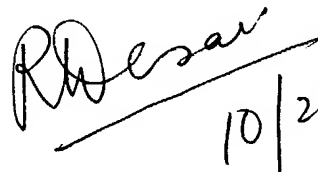
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai  
Primary Examiner  
Art Unit 1625

R.D.  
October 29, 2004

  
10/29/04